

March 23, 2021

**Via ECF**

The Hon. Robert J. Kugler  
United States District Judge  
USDC, District of New Jersey  
Mitchell H. Cohen Building & U.S. Courthouse  
4<sup>th</sup> & Cooper Streets, Room 1050  
Camden, NJ 08101

Special Master the Hon. Thomas Vanaskie  
Stevens & Lee  
1500 Market Street, East Tower, 18th Floor  
Philadelphia, PA 19103

The Hon. Karen M. Williams  
United States Magistrate Judge  
USDC, District of New Jersey  
Mitchell H. Cohen Building & U.S. Courthouse  
4<sup>th</sup> & Cooper Streets, Room 1050  
Camden, NJ 08101

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*  
USDC, District of New Jersey, No. 1:19-md-2875-RBK-KMW

Dear Judge Kugler and Special Master Vanaskie:

I write on behalf of the Defendants' Executive Committee to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on Wednesday, March 24, 2021.

**1. Defendants' Request for Guidance Regarding Dismissal of Certain Cases Pursuant to Motion to Dismiss Order No. 5**

In Motion to Dismiss Order No. 5 (Order No. 5) (ECF 839), the Court granted Defendants' Motion to Dismiss, in part, and dismissed, with prejudice, all claims arising under Louisiana law, as subsumed by the Louisiana Products Liability Act (LPLA), and all claims under the New Jersey Consumer Protection Act. These dismissals with prejudice apply to all of the claims asserted in

complaints filed individually by approximately 39 Louisiana plaintiffs.<sup>1</sup> Thus, the dismissal of those complaints is final, and they may not be revived by amendment under Fed. R. Civ. P. Rule 15. *See Smith v. Kershentsef*, No. 19-3893, 2021 WL 400148, at \*2 (3d Cir. Feb. 4, 2021) (explaining that dismissal with prejudice is final judgment on the merits); *Petrossian v. Cole*, 613 F. App'x 109, 111 (3d Cir. 2015) (“A dismissal with prejudice constitutes an adjudication on the merits ‘as fully and completely as if the order had been entered after trial.’”); *see also Suddreth v. Mercedes-Benz USA, LLC*, CA No. 10-cv-05130, 2012 WL 13034279 (D.N.J. July 31, 2012) (noting that dismissal with prejudice is final judgment barring amendment under Rule 15).

Defendants request the Court’s guidance as to whether another order dismissing the Louisiana complaints by caption is necessary. Defendants find it necessary to seek immediate guidance on this issue, as five of the Louisiana cases were selected for the initial bellwether pool of 28 cases prior to the Court’s dismissal ruling and this issue directly impacts the discussion of the Bellwether processes discussed below. *See* Tr. 2/24/21 CMC, 60:1-3 (THE COURT: “we lost some bellwether cases because of the Court’s – one of the Court's motions to dismiss decisions.”).

Defendants invited Plaintiffs to meet and confer on this issue, or to provide their views, and then informed Plaintiffs that Defendants intended to seek the Court’s guidance on this issue. *See* Goldberg emails dated 3/22/21 and 3/21/20, attached as Ex. A.

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<sup>1</sup> Each Louisiana Personal Injury plaintiff was required to file a Short Form Complaint where they were allowed to select the causes of action they allege from a provided list. Included in the list was: “Other State Law Causes of Action as Follows:” where a plaintiff could have listed a cause of action under a state’s PLA; no Louisiana plaintiff listed in the Proposed Order chose to select that option and bring a cause of action under the LPLA.

## **2. Bellwether Trial Pool Order**

Defendants seek entry of the attached proposed Draft Order Establishing Trial Pool (“Draft Order”) (attached as Ex. B), which memorializes the parties’ agreement regarding the initial Bellwether process. As discussed at the February 24, 2021 Case Management Conference, the parties met and conferred over a process for selection of plaintiffs for a Bellwether Trial Pool. By agreement, on January 15, 2021, counsel for each side simultaneously disclosed fifteen (15) personal injury plaintiffs for inclusion in the Bellwether Trial Pool. The parties’ respective disclosures are attached as Exhibits C and D. Plaintiffs and Defendants disclosed two of the same picks (as a result of the Parties’ compromise to choose five selections from **Plaintiffs’** original pool of DFS-request Plaintiffs), resulting in a total of twenty-eight (28) cases in the Bellwether Trial Pool. Subject to the Court’s approval, the parties have memorialized these selections in the attached proposed Draft Order Establishing Trial Pool (“Draft Order”) (Ex. B).

The parties have agreed as to the language of the Draft Order, except for the dismissal provision of paragraph 7, which remains in dispute. Previously, Defendants had proposed a draft order that stated: “Bellwether Trial Pool cases may be dismissed only by court order, on terms that the Court considers proper. In the event this Court permits a Bellwether Trial Pool case to be voluntarily dismissed, the Party who selected that case for the pool may pick a replacement case from the entirety of the personal injury cases filed in or transferred to the MDL.” Plaintiffs’ only objection to the proposed language was the provision requiring court approval for voluntary dismissals. Plaintiffs joined in Defendants’ proposal that dismissed Bellwether pool cases be replaced by the party who selected that case. Plaintiffs stated specifically in their February 23, 2021 CMC submission:

The Parties have held productive meet and confer sessions to discuss issues associated with the entry of a Bellwether order. **With respect to this order, the only remaining dispute between the parties concerns dismissal procedures for Bellwether cases. Defendants suggest that Bellwether cases may only be dismissed by court order on terms that the Court considers proper.** Plaintiffs believe this language is unnecessary. In the Benicar litigation, cases were selected for the bellwether pool by random selection. There, the Court allowed bellwether cases to be dismissed and to be replaced again by random selection. Here, the parties have each selected a set of cases for work-up. **Thus, Plaintiffs propose that if a Bellwether case is dismissed, the party who selected that case for the pool may pick a replacement. This procedure would allow Defendants to re-select a case for the pool if a case in their original selection is dismissed, thereby alleviating the concern that dismissal of a case in the Defendants' set would upset the balance of the pool.**

*See* Pl's CMC Submission, dated February 23, 2021 at p. 3 (Ex. E) (emphasis added). Following the Court's guidance at the February 24, 2021 CMC, and instruction to the Parties to continue conferring on the language of the proposed order, Defendants removed the language requiring court approval for voluntary dismissals and resubmitted the draft to Plaintiffs. *See* Tr. 02/24/21 CMC, 69:6-8.

Defendants' current proposed order states: "If a Bellwether Trial Pool Case is dismissed, the Party who selected that case for the pool may pick a replacement from the entirety of the personal injury cases filed in or transferred to the MDL. Replacement cases should be picked no less than four months prior to the operative deadline to complete the second phase of fact discovery or by other deadline by consent of the parties or court order. *See* [CMO No. 23](#), dated 2/11/21." As cited above, this language is entirely consistent with Plaintiffs' proposal that **"if a Bellwether case is dismissed, the party who selected that case for the pool may pick a replacement."** *See* Pl's CMC Submission, dated February 23, 2021 at p. 3 (Ex. E). Defendants' proposed order simply adds a timeframe for the replacement of the cases, to ensure there is enough time to conduct

discovery in the cases prior to discovery deadlines. Defendants are fully willing to meet and confer over the exact time period for replacement picks but have not received any reaction from Plaintiffs to the timing provision.

After not receiving consent from Plaintiffs to the revised proposed Order, the parties met and conferred on March 22, 2021. Despite unequivocally agreeing with party-selected replacement picks at last month's CMC, Plaintiffs inexplicably reversed position on the method for replacement picks, now arguing that replacements are not needed for the pool of twenty-eight, or if they are replaced, it should be by random selection. Thus, even though Defendants revised paragraph 7 to comply with the Court's guidance, Plaintiffs continue to object to the language of paragraph 7 and will not agree to the Order documenting the parties' efforts to date.

Plaintiffs' reversal of position regarding dismissals and replacement picks, seems to be driven by the recognition that their new proposed Bellwether Trial Plan, discussed below, is wholly inconsistent with the Parties' negotiations, agreements and representations to the Court to date. The Court's scheduling order, set forth in CMO 23, entered on February 11, 2021, provides that ten of these twenty-eight Plaintiffs will be deposed by June 1, 2021, with the remaining Plaintiffs and Plaintiff-specific fact discovery to be completed by October 4, 2021. Defendants are in the process of scheduling these Plaintiff depositions, with depositions currently scheduled on April 13, 20, and 28. Regardless of the process for any further winnowing of the trial pool prior to trial, which should be subject to further meeting and conferring, an Order memorializing the initial selection process, and a provision for replacement of dismissals, needs to be entered without further delay.

### **3. Plaintiffs' Newly Proposed Bellwether Trial Plan**

As a preliminary matter, Defendants believe it is premature for the Court to rule upon Plaintiffs' newly proposed Bellwether Trial Plan, given the parties have had limited opportunity to meet and confer over the proposal and there is no immediate need for finalizing a complete trial sequencing process. Nonetheless, because Plaintiffs have raised this with the Court now, Defendants will address Plaintiffs' newly proposed plan.

Despite progress made to date, now in what can only be interpreted as an attempt to reduce Plaintiffs' discovery burdens, on March 3, 2021, Plaintiffs sent Defendants a letter proposing a "Bellwether Trial Plan," which attempts to undo the parties' progress in fashioning a reasonable Bellwether plan to date. As reported the Court at the CMCs on January 27, 2021 and February 3, 2021, and the Parties worked diligently to agree on the process that resulted in a pool of twenty-eight Plaintiffs for case specific work-up. Now, apparently realizing that the Court's CMO 23 allows Defendants to proceed with taking the depositions of these twenty-eight Plaintiffs and Plaintiff-specific third-parties by October 4, 2021, Plaintiffs are scrambling to prematurely reduce the number of bellwether pool Plaintiffs, so that they do not have to conduct this discovery. But Plaintiffs' proposed Bellwether Trial Plan raises a number of practical concerns, as well as potential prejudice to Defendants.

Plaintiffs' newly proposed plan provides that the pool of 28 bellwether cases would be winnowed to just eight via random selection, following the completion of Plaintiff depositions, and no other discovery. Prior to receiving this letter, Defendants' understanding, based on a reasonable reading of CMO 23, was that all 28 cases in the Bellwether Trial Pool would proceed through Plaintiff-specific fact discovery. Presumably, in the meantime the Parties would meet and

confer on a process for further winnowing and sequencing the cases for trial, once the Parties had more information about these cases.

Accordingly, Defendants responded to Plaintiffs' new proposal, objecting to the winnowing of the pool at this early stage and setting out their position that such discussions are premature. *See* Letter from Ms. Lockard to Mr. Williamson, dated March 19, 2021 (attached as Ex. F). Defendants noted that they do not oppose a winnowing of the Bellwether Trial Pool at a later stage, after sufficient discovery is completed for the Parties to more accurately assess the strengths and weaknesses of the cases and their representativeness of the cases in the overall pool. Though Defendants believe it is premature to present an alternative proposal for winnowing, at a minimum Defendants' counterproposal would incorporate the following concepts:

1. Allow for the completion of some degree of Plaintiff-specific discovery on the 28 agreed Bellwethers prior to the next stage of winnowing;
2. Allow the Parties some input into the selections, or strikes, taking into account the discovery obtained;
3. Result in a final Bellwether set of more than 8, perhaps as many as 12 or 14, to be randomly sequenced by the Court for trial given the number of Defendants and distribution scenarios that are involved; and
4. So-called "joint picks" should not automatically be included in the winnowed trial pool set.

First, Plaintiff-specific discovery of these twenty-eight agreed Plaintiffs should proceed according to the terms of CMO 23, and second, the Parties should be allowed subsequent input in a further winnowing to ensure representative cases remain in the pool. To date, Defendants and

the Court know very little about these cases, as medical records and Plaintiff's Fact Sheets are still being provided and updated. As Defendants have pointed out, discovery may reveal certain cases in the Bellwether Trial Pool are not appropriately representative trial cases. For example, depositions of treating physicians may reveal that certain cases involve idiosyncratic Plaintiff-specific issues. Discovery will allow the Parties to better identify which of these twenty-eight cases are appropriate trial candidates, and reduce that number to a manageable set to be sequenced for trial.

While Defendants are open to further negotiations over the amount of discovery that should be allowed as to each of the twenty-eight Plaintiffs prior to the next stage of winnowing, Defendants believe at a minimum they should be allowed to take Plaintiffs' depositions and the depositions of their key prescribers and treaters. Defendants are willing to consider a reasonable limitation on the number of treating physician depositions (for example, two to three for most cases absent good cause shown for more). Plaintiffs indicated, though, that they oppose **any** depositions beyond Plaintiff depositions prior to a winnowing of the pool, and therefore are unwilling to consider compromise proposals.

Third, Defendants believe the ultimate trial pool needs to be larger than eight cases in order to provide a panel of cases that adequately represents a sufficient array of Defendants and distribution chains, given the large number of finished dose manufacturers, API suppliers, and downstream Defendants in this litigation. Unlike a single-defendant MDL, such as Benicar (where there were ten final bellwether trial plaintiffs), this litigation warrants a slightly larger pool, which could then be randomly sequenced by the Court for trial.



Moreover, there will likely be some natural winnowing of the pool of twenty-eight over the course of discovery. Both Parties recognize that as discovery progresses, some cases may be dismissed, either voluntarily or by Court order. (For example, the Court's Order No. 5 on Defendants' Motion to Dismiss holding that all Louisiana Plaintiff claims are subsumed by the Louisiana Products Liability Act, could result in the loss of at least five current Bellwether pool Plaintiffs). Additionally, through further discovery, certain Plaintiffs may drop out or certain Defendants be dismissed from individual cases due to lack of product ID or other reasons. Therefore, premature winnowing to an unreasonably small number may result in the Parties being left with an inadequate source of representative cases that have been properly worked up for trial.

During the Parties' March 22<sup>nd</sup> conference, Plaintiffs suggested that dismissed cases from among the limited pool of eight be replaced with another case in the larger pool of twenty-eight, with Plaintiff picks being replaced by another Plaintiff pick and Defendant picks by a Defendant pick. Under Plaintiffs' plan, however, little or no workup would have been done in the potential replacement cases. Plaintiffs have not explained how discovery in the replacement cases could be completed by the current discovery deadlines, and certainly not on the same timeline as the original cases in the pool, particularly if a case is dismissed months from now. This could result in a very small pool of cases being trial-ready when the Court is ready to proceed with bellwether trials. If the Bellwether pool is prematurely winnowed to eight cases for work-up, it is likely that, as dismissals and substitutions occur even fewer cases will be trial-ready when the Court is ready to proceed with bellwether trials (which could be accelerated if class certification is denied and the class actions do not reach trial). Maintaining the larger pool of twenty-eight through discovery and ensuring a sufficient number of trial cases remain "live" will help remedy these concerns.

Finally, Defendants object to the provision in Plaintiffs' new proposal calling for the automatic inclusion of the two so-called "joint picks" in the winnowed pool of eight. Defendants would be prejudiced by such a provision. These two cases are in essence Plaintiffs' picks, as they were part of Plaintiffs' original DFS selections. These two cases were included in the Bellwether Trial Pool as a result of a compromise between the Parties to avoid waste of the resources expended by the workup of these Plaintiff-picked cases and to ensure that ten Plaintiff depositions could be completed within the deadlines set forth in CMO 22. These are not truly "joint picks" from the docket at large. Notably, six other cases in the pool of 28 were also picked as a result of this compromise and are therefore skewed in favor of Plaintiff. This is another reason Defendants should have input into the final, winnowed selections, rather than blind random selection, in order to account for this imbalance.

Overall, Plaintiffs' new proposal presents a number of details and complications that are premature, unnecessary, unfair to Defendants, and contradictory to the Parties' and the Court's discussions to date. Looking at the bigger picture, it is clear Plaintiffs' motivation in presenting this new proposal is to revisit the allowable Plaintiff discovery under the Court's CMO 23, take the focus off of the personal injury claims, and to minimize Plaintiffs' obligation to participate in discovery.

However, the Court has already announced that discovery should proceed on the bellwether pool and that the cases will be sequenced for trial by random-selection closer to the trial phase. In fact, Judge Kugler even suggested that discovery could commence on as many as forty bellwether plaintiffs:

I agree with defendants that they should suggest 20 potential plaintiffs so you have a total of 40 plaintiffs, **which you're taking discovery on** for the personal injury cases. Where that leads, I don't know yet. It would certainly be preferable if we're going to do bellwether trials to choose the trials from that 40, but my experience with that has not been satisfactory because you end up with a lot of cases getting dismissed when they're listed for trial. So what I -- what I will do is, I will make random selections if we get to that stage of bellwether trial for that.

Tr. 11/24/20 CMC, 15:7-15 (emphasis added). Judge Kugler wisely recognized that discovery has to proceed on a larger number of cases, given the natural winnowing via dismissals, and that random sequencing for trial is likely necessary, but the Court left open for another day whether there will be any additional "choosing" in the interim.

Additionally, as Defendants have said before, Plaintiffs' depositions and their treaters' depositions are certainly necessary and relevant to finalization of Defendants' expert reports and *Daubert* challenges. The Court has also specifically rejected Plaintiffs' repeated argument that workup of individual personal injury cases, or general causation, should be stalled or phased until later. The Court has made clear repeatedly that the personal injury cases and general causation should be worked up on a parallel track along with the consumer class actions, while acknowledging that this would require work and appropriate staffing:

It is my intention that the November conference, at the end of November, to enter an order governing discovery on the general causation/bodily injury claims. I also agree with defense counsel that there needs to be sometime mid next year, service of expert reports on those issues and *Daubert* hearings, if necessary. So what I'm telling you is, that you need to continue discussing this with the eye towards the November status conference, late November status conference, the Court entering an order governing the discovery on that parallel track. It's going to have to be parallel. We're not taking any resources away from the discovery and all the work that needs to be done that's already scheduled and set up. So sounds to me like you're going to have to get a whole other army of lawyers involved to do that kind of discovery in those other issues, but that's where we're going to go with this in the future.

Tr. 09/30/20 CMC, 49:13-50:4.

In sum, Plaintiffs' "Bellwether Trial Plan" is merely an effort to end-run around the Court's instruction that discovery and work-up of the agreed-upon personal injury bellwether pool should proceed. To the extent that further winnowing and sequencing needs to occur before trial, a point Defendants do not necessarily dispute, the Parties can continue to meet and confer on those processes and/or the Court can decide at a time closer to trial, once more is known about the pool of twenty-eight and any dismissals or adjustments to the Parties have occurred.

#### **4. Downstream Defendants' Obligations Regarding Defendant Fact Sheets**

The Wholesaler Defendants' defense fact sheet ("Wholesaler DFS") entered by the Court (Dkt. 546, Ex. C) includes a very specific procedure for the completion of defense fact sheets by Wholesaler Defendants. That procedure was heavily negotiated among the parties and ultimately entered by the Court. It includes the provision that a Wholesaler Defendant is only required to complete a defense fact sheet in instances in which the Wholesaler Defendant has been identified in a Retailer Defendant defense fact sheet. (See [Dkt. No. 546](#), Ex. C, p. 1 ("[w]ithin 60 days of completion of a Defendants' Fact Sheet by all Pharmacy or Retailer Defendants, each Wholesaler, Repackager, and Relabeler Defendant . . . identified in a Defendant Fact Sheet by any Retailer or Pharmacy as an entity in the chain of distribution for drugs purchased and/or consumed by a particular Plaintiff must complete and serve this Defendant Fact Sheet ("DFS") on each Plaintiff's counsel . . .").) The process makes sense, otherwise, without the data from a Retailer Defendant identifying a Wholesaler Defendant(s) as an entity in the chain of distribution, every Wholesaler Defendant would be required to search its data to determine whether it was or was not potentially in the chain of distribution of a VCD received by a plaintiff at issue. That type of broad

inefficiency was resolved through the careful and significant negotiation of the Wholesaler DFS by all parties.

Now, contrary to the carefully negotiated and detailed procedure for the Wholesaler DFS, Plaintiffs' counsel requests that each Wholesaler Defendant complete a DFS in four separate bellwether cases in which no Retailer Defendant has been named and, as a result, in which no Retailer Defendant defense fact sheet has been served so no Wholesaler has been identified as being in the chain of distribution. In those four cases, Plaintiffs' counsel is seeking to require each Wholesaler Defendant (none of whom are named in any of the four Plaintiffs' short form complaints) to do exactly what the parties specifically negotiated the Wholesaler DFS to avoid – i.e., non-targeted, burdensome discovery directed to all Wholesaler Defendants collectively, untethered to any data from a Retailer indicating whether a Wholesaler Defendant is potentially in the chain of distribution for a particular VCD.

In response to Plaintiffs' counsel's request, Wholesaler Defendants proposed that Plaintiffs in those four cases use authorizations or Rule 45 subpoenas to obtain information from the non-party Retail Pharmacy from which Plaintiffs obtained the VCD(s) at issue, to determine from which entity each Retail Pharmacy sourced its VCD(s). That readily available information will indicate which Wholesaler Defendant, if any, was potentially in the chain of distribution, and will allow Plaintiffs' counsel to appropriately target a request for a Wholesaler DFS as indicated by the Pharmacy purchase data. Plaintiffs' counsel has stated that they are opposed to conducting non-party discovery of the unnamed Retail Pharmacies because they believe there is insufficient time to do so in advance of the depositions of the four Plaintiffs at issue.

While Wholesaler Defendants do not agree that Plaintiffs are unable to obtain non-party discovery from the Retail Pharmacies at issue in the time provided, nevertheless, Wholesaler Defendants are cognizant of the time pressure issues Plaintiffs face (albeit of their own making) in these four cases. As such, Wholesaler Defendants are amenable to the negotiation of a limited written agreement by which they will search their data and prepare expedited Wholesaler DFSs in the four cases at issue, and only those four. Wholesaler Defendants request that the Court provide the parties until April 14, 2021, to reach an agreement.

## **5. Discovery Issues**

Plaintiffs have indicated that they intend to raise various Defendant-specific discovery issues at the Case Management Conference. The following is a summary of the Defendants' positions with regard to the issues Defendants anticipate will be raised. Defendants reserve the right to supplement this summary to the extent Plaintiffs identify additional discovery issues in their submission that are not expressly addressed herein.

### **a. Hetero**

Counsel for Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. (collectively, "HLL") has significantly narrowed the remaining issues and anticipates resolving all of Plaintiffs' outstanding concerns.

Since our last Status Letter to Judge Vanaskie on March 16, 2021, HLL has made several supplemental document productions to remedy the metadata and document deficiency issues raised by Plaintiffs. On March 16, 2021, HLL produced documents responsive to the third-party subpoena served upon the foreign entity Analys Lab, and further supplemented that production on March 19, 2021. As of today, HLL's Analys Lab Production is now complete.

Additionally, on March 19, 2021 HLL remedied a metadata deficiency flagged by Plaintiffs' Counsel, and corrected the "File\_Extension" metadata field in all of its prior productions. Further, on March 22, 2021 HLL re-produced "Annexures" that were previously deemed non-responsive in HLL's prior document production. Thereafter, on March 23, 2021, HLL produced its Second SOP Production, which included most of the SOP-related documents Plaintiffs have requested including prior and subsequent versions of SOPs as well as Site Master Files. HLL has informed Plaintiffs that it intends to make a subsequent document production by the end of the day today, its Third SOP Production, which will encompass all remaining SOP-related documents that Plaintiffs have requested including additional SOPs, Site Master Files, and relevant Quality Manuals. Finally, on March 23, 2021 HLL provided a final Cast of Characters.

Accordingly, HLL has worked diligently to address each and every issue identified by Plaintiffs. HLL is confident that any remaining issues can be addressed in a subsequent meet and conferral with Plaintiffs and HLL is prepared to move forward with depositions as early as possible.

**b. Mylan**

In November 2019, the Court decided a number of "Macro Discovery" issues. The purpose of these rulings, which were memorialized in an Order ([Dkt. No. 303](#)), was to define the outer limits of the Manufacturer Defendants' discovery obligations in this litigation. Since then, Plaintiffs have repeatedly attempted to expand discovery beyond that scope. In Plaintiffs' latest attempt to circumvent the Marco Discovery Order, Plaintiffs have demanded that Mylan produce FDA correspondence related to a Mylan facility – Unit 7 – that never manufactured a single batch of valsartan active pharmaceutical ingredient ("API") or finished dose medication. Documents

concerning Unit 7 are beyond the scope of the Court's Macro Discovery Order, and have no relevance to this litigation. Accordingly, Plaintiffs' request for discovery into Unit 7 should be denied.<sup>2</sup>

This Court's Macro Discovery Order is crystal-clear with regard to the manufacturing facilities that are at issue in this litigation:

As to defendants, **the facilities at issue for discovery purposes are the facilities that manufactured Valsartan API and Valsartan sold in the United States**, not just the facilities that sold recalled Valsartan.

Dkt. No. 303 (emphasis added). Further, during the CMC where the Parties argued the Macro Discovery Issues, the Court summarized the parties' positions:

Defendants want to limit discovery to only the API facilities that made Valsartan that was recalled. In defendants' papers, they argue they also want to hold off on discovery regarding the finished dose manufacturing facilities until plaintiffs' document requests are served, albeit this position may have changed during oral argument.

Plaintiffs want discovery from every entity and manufacturing facility in the Valsartan distribution chain; in other words, as plaintiffs write, "Every facility with any role for Valsartan."

Starting with defendants' API manufacturing facilities, the Court rules that every facility that manufactured Valsartan API that was sold in the United States is a proper subject of discovery and not just those facilities that manufactured Valsartan that was recalled.

Tr. 11/20/21 CMC, 12:25-13:14. Notably, neither Plaintiffs, Defendants, nor the Court ever contemplated that Plaintiffs would be entitled to discovery related to a facility that did not manufacture valsartan sold in the United States.

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<sup>2</sup> This topic was initially discussed during the March 10, 2021 Case Management Conference. At that time, the Court indicated that it had not reviewed any of the Unit 7 documents in question, and therefore, it was premature to decide the issue. Tr. 3/10/21 CMC, 49:12-16.



During the relevant time period, Mylan manufactured valsartan API at two facilities in India: Unit 8 and Unit 3. Mylan's finished dose valsartan was manufactured at three other facilities, two of which are located in India (Aurangabad and Nashik), and one in the United States (Morgantown, West Virginia). The vast majority of Mylan's valsartan API was manufactured at Unit 8, which is located in Andhra Pradesh, India. In contrast, Mylan did not manufacture any valsartan API or finished dose at Unit 7, which is located in Hyderabad, India, nearly 200 miles away from Unit 8. As a result, Unit 7 is unequivocally beyond the scope of the Court's Macro Discovery Order.

In an attempt to establish good cause for their fishing expedition regarding Unit 7, Plaintiffs rely on the fact that both Unit 8 and Unit 7 purchased a recovered solvent from the same third-party vendor during the relevant time period. Plaintiffs point specifically to an Establishment Inspection Report issued by FDA to Unit 7 that includes a single passing reference to a separate inspection conducted by FDA at Unit 8 following the discovery of trace amounts of a nitrosamine impurity in valsartan API. Based on this purported connection, Plaintiffs have requested that Mylan produce all correspondence with FDA related to this inspection.

While Plaintiffs will assert that this "discrete" request for production of only a few documents does not create any burden on Mylan, that argument misses the point. These inspection documents have no relevance to this litigation and are not a proper subject of discovery. The FDA inspection of Unit 7 that is at issue occurred in February 2020 – more than two years after Mylan (i) recalled its valsartan in the US market, and (ii) stopped using recovered solvent in the manufacture of its valsartan API. Further, the Unit 7 inspection occurred **after** the FDA conducted

its inspection of Unit 8 related to the valsartan recall. Mylan has already produced all FDA correspondence related to Unit 8, including drafts and internal communications related thereto.

Moreover, although the present dispute concerns only formal correspondence between Mylan and FDA related to the 2020 Unit 7 inspection, Plaintiffs have already indicated that this is just the tip of the iceberg. Once Plaintiffs have the FDA correspondence, they will undoubtedly seek additional documents related to Unit 7.

The federal rules do not permit Plaintiffs to obtain documents merely to satisfy their curiosity. Unit 7 did not manufacture valsartan. An FDA inspection at Unit 7 that occurred years after any of the relevant events in this litigation is not the proper subject of discovery. The Court tailored the discovery framework in this case, including “core discovery” and the Macro Discovery Order, to foreclose this type of fishing expedition into extraneous areas. *See, e.g.*, Tr. of 4/10/19 CMC, 31:14-17 (noting that one purpose of Defendants’ production of “core discovery” was to “guide [Plaintiffs’] discovery in this case so [Plaintiffs] don’t go down a rabbit hole.”); Tr. 11/20/19 CMC, 20:24-21:1 (stating, “[t]he case involves sales of Valsartan in the United States and that is where the focus of plaintiffs' discovery should and will be.”). For this reason, the Macro Discovery Order limited discovery to the facilities that manufactured valsartan for the United States market. Plaintiffs cannot establish good cause for the Court to re-write that Order with regard to Unit 7.

**c. Aurobindo**

On March 16, 2021, Aurobindo Pharma Ltd. (“APL”) filed a Status Report regarding their collection of custodial documents located in India. APL continues to make every effort to obtain clearance for the hard drives currently held in customs. APL has received the replacement

encrypted hard drives and copies are being made. We should hopefully start getting shipments soon. KLDDiscovery is prepared to sign an affidavit regarding the events that transpired regarding the shipments of the hard drives.

Since the mid-month conference, Plaintiffs have sent counsel for the Aurobindo parties five separate emails regarding various purported document production deficiencies, most of which were raised for the first time, and have threatened to seek relief from the Court on all issues unless all documents are produced immediately. Plaintiffs' alleged issues include, among others, Aurobindo's Privilege Log, contracts with customers, purchasing information, and a list of purportedly "improperly withheld documents." All of these were raised for the first time after the mid-month conference on March 10, 2021. Defense counsel emailed Plaintiffs' counsel to let them know that the Aurobindo defendants are hopeful the parties will be able to resolve most if not all of the issues without having to seek the Court's intervention and that they do not view any of Plaintiffs' issues as ripe for the Court's involvement. Nonetheless, Plaintiffs insist on raising all issues unless all documents are produced today.

We told Plaintiffs that we would review their lists of purportedly improperly withheld documents and offered to meet and confer later this week or early next week. We also told Plaintiffs that we will be supplementing Aurobindo's document production with customer contracts. We anticipate that these will be produced early next week if not by the end of this week. We are attempting to resolve these issues in good faith with Plaintiffs by re-reviewing documents and offering to meet-and-confer. They have not filed a motion and they just raised these issues with us. We remain hopeful that the parties can work this out without Court intervention.

In addition, Plaintiffs would like the Aurobindo parties to supplement their production of Standard Operating Procedures. On March 4, 2021, the Aurobindo parties produced over 80,000 pages of Standard Operating Procedures. Nonetheless, they are reviewing Plaintiffs' list and offered to meet and confer. We would like the opportunity to continue to meet and confer with plaintiffs and propose that any remaining disputes be resolved at the mid-month April conference.

Counsel for the Aurobindo parties will be prepared to discuss the work product and attorney-client privilege issues concerning the documents from Meridian Consulting and ToxRox Consulting at the Case Management Conference.

**d. Retailer Defendants**

Following the last case management conference, on Friday, March 12, Plaintiffs' counsel sent the Pharmacy Defendants a letter responding to the Pharmacy Defendants' February 16 letter regarding the Plaintiffs' draft Requests for Production. Counsel for the Pharmacies have conferred with each other, and with their respective clients, and are preparing a response. The Pharmacies anticipate sending that letter to Plaintiffs later today, or tomorrow. As directed by Judge Vanaskie at the last conference, the Pharmacies will attempt to confer with Plaintiffs regarding which draft Requests can or should be negotiated now, and which Requests it makes more sense to table while the pleadings are in flux. Plaintiffs also have requested that the Pharmacies send comments regarding Plaintiffs' draft 30(b)(6) topics. The Pharmacies are taking a similar approach to that draft, and are conferring internally to prepare a consolidated set of comments and edits to the draft topics for Plaintiffs' consideration, including comments regarding which topics should be tabled for further discussion until after there is additional clarity on the pleadings.

**e. Wholesaler Defendants**

As directed by the Court, on Friday March 12, 2021, Plaintiffs' counsel sent Wholesaler Defendants a letter responding to the February 16, 2021 letter regarding Plaintiffs' draft Second Requests for Production. Counsel for Wholesaler Defendants conferred, and are preparing a red-line of Plaintiffs' proposed Second Requests for Production. Wholesaler Defendants anticipate sending that red-line version of the Second Requests for Production to Plaintiffs' counsel in advance of the March 24, 2021 status conference. As directed by the Court at the last conference, counsel for Wholesaler Defendants will confer with Plaintiffs' counsel about those Second Requests for Production that can be negotiated at present, and those which are more appropriate to consider and potentially negotiate after the pleadings and remaining causes of action against Wholesaler Defendants are more clearly defined. Wholesaler Defendants also continue to evaluate Plaintiffs' draft Rule 30(b)(6) topics.

**6. Plaintiff Fact Sheet Show-Cause Submission**

**Cases Addressed at the February 24, 2021 Case Management Conference:**

Defendants note that the Court issued six show cause orders returnable at the March 24, 2021 Case Management Conference.

The issues in one case have been resolved and the order to show cause may be withdrawn:

- Patterson, Linda – 20-cv-14605

These five cases remain subject to an order to show cause at the March 24, 2021 Case Management Conference for failure to substantially complete a PFS:

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Notice Sent
1.	Gibson, James	20-cv-2875	Douglas & London	Failed to file amended fact sheet or respond to Deficiency Notice	12/28/20
2.	Medrano, Rene	20-cv-12099	Fears Nachawati	<p>I.C.1 - Plaintiff produced pharmacy records from Mid Valley Pharmacy that demonstrate use of Amlodipine, however Plaintiff has identified use of Amlodipine/Valsartan in the PFS. Please produce proof of use of the identified Amlodipine/Valsartan product. Also, the produced pharmacy records do not include NDC codes. Please produce pharmacy records or other documentation that includes NDC codes. In addition, an authorization for Mid Valley Pharmacy was not provided.</p> <p>I.C.4 – Failed to provide the NDC Code for the second identified product.</p> <p>I.D.1 - Plaintiff did not produce medical records for the following identified health care provider: Dr. Habib Ghaddar. Please produce complete medical records for the foregoing identified health care provider.</p> <p>II.D.4.c - Failed to provide the dates of exposure in Plaintiff's diet including red and/or processed meats. Plaintiff's answer is cut off on the PFS form in the Third Amended PFS. Please provide the complete answer and include a supplemental page if the answer will not fit on the PFS form.</p> <p>III.G.a – III.G.c - Plaintiff failed to provide substantive responses to the requests regarding the medical expenses he is seeking recovery for. Plaintiff indicated in the PFS that billing records have been requested. Please provide the medical</p>	12/10/20

				<p>expense information and the billing records as they become available.</p> <p>XI.A.1 – Failed to provide healthcare authorizations for the following: Dr. Ricardo Lerma; Benjamin Salinas; Pamela Lopez FNP; Dr. David E. Yardley; Dr. Christopher Wood; Dr. Debra Woloski; Dr. Habib Ghaddar; Mid Valley Pharmacy; Walgreens; Walmart.</p> <p>XI.A.7 – Plaintiff produced a mental health records authorization for Jose Igoa, MD, however the produced mental health records authorization is dated. Please produce a properly executed and undated mental health records authorization for Jose Igoa, MD.</p> <p>XI.B.2 - No pharmacy records were produced for the following identified pharmacies: Walgreens or Walmart.</p> <p>XI.B.9 - No photographs of the packaging or labeling for the identified Amlodipine Valsartan product was produced. Plaintiff only produced photographs of labeling for a Losartan product.</p> <p>XI.B.18 - No medical expense records were produced. Plaintiff indicated in the PFS that billing records have been requested. Please produce the billing records as they become available.</p>	
3.	Greenleaf, Robert	20-cv-8785	Hollis Law	No PFS Filed	PFS Due - 11/28/20
4.	Jackson, Rickey	20-cv-14927	Levin Papantonio	No PFS Filed	PFS Due - 12/22/20
5.	Newcombe, Sonja	20-cv-10274	Levin Papantonio	No PFS Filed	PFS Due - 8/11/20

**Second Listing Cases – Order to Show Cause Requested:**

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these three cases were previously listed on the agenda for a prior CMC. Defendants provided a list including these cases and identified deficiencies to Plaintiffs' leadership counsel for distribution on March 16, 2021, met and conferred with Plaintiffs' counsel on March 19, 2021, and have been available for further meet and confers as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why the case should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the March 24, 2021 Case Management Conference:

	<b>Plaintiff</b>	<b>Civil Action No.</b>	<b>Law Firm</b>	<b>Deficiencies</b>	<b>Deficiency Notice Sent</b>
1.	Thompson, James	20-cv-114554	Arnold & Itkin, LLP	III.G.c - Failed to respond.  Expenses for labs, CT of chest, and colon surgery incurred at Henry Ford Hospital.  VIII.A.4 - Failed to respond.  Dates of cancer diagnoses for mother and father.	01/05/21
2.	Wilcox, John	20-CV- 17939	Babin Law Group	No PFS Filed	Due - 02/02/2020
3.	Williams, Naomi	20-CV- 08772	Levin Papantonio	No PFS Filed	Due - 09/18/2020

**First Listing Cases – Remaining Core Deficiencies:**

The following Plaintiff Fact Sheets contains core deficiencies which remain unresolved. Defendants provided a list including these cases and identified deficiencies to Plaintiffs on March 16, 2021 and met and conferred with Plaintiffs' counsel on March 19, 2021 and have been available



for further meet and confers as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

	<b>Plaintiff</b>	<b>Civil Action No.</b>	<b>Law Firm</b>	<b>Deficiencies</b>	<b>Deficiency Notice Sent</b>
1.	Cunningham, Kristine	2020 - CV-12812	Brown LLC	HIPAA authorizations need to be filled out to providers listed in PFS – not blank.	2/18/21
2.	Williams, Taffnie	2020 - CV-20380	The Donahey Firm	No authorizations. PFS substantially incomplete.	3/12/21
3.	Day, Peter Townsend	20-cv-19777	Rheingold Giuffra Ruffo Plotkin LLP	<p>III. H Failure to provide response regarding specialized economic damages.</p> <p>IV. E Failure to provide response regarding witnesses.</p> <p>V. A, C Failure to provide responses regarding weight.</p> <p>VI. B Failure to provide any response regarding OTC medications.</p> <p>XI. A. 1 Failure to provide completed authorizations for each healthcare provider.</p> <p>XI. A. 6 Failure to provide completed insurance authorization.</p> <p>XII Failure to provide executed Declaration page.</p>	2/29/21
4.	Mundy, Gwendolyn	20-cv-08285	Watts Guerra LLP	III. G. C Failure to itemize or provide amount of medical expense(s).	2/26/21

5.	Cassaras, Ronald	20-cv- 08774	Hollis Law Firm	I. C. 16 Failure to provide records demonstrating Product ID.  XII Failure to provide dated Declaration page.	2/19/21
6.	Stewart, Pamela	20-cv- 03788	Erlanger Law Firm PLLC	I.D.1 - Failed to attach records.  Medical records in your possession demonstrating alleged injury, this is a personal injury action.  I.D - Failed to respond.  Section D – Alleged Injury; this is a personal injury action.  III.G.a - Failed to respond.  Medical expenses.  V.G.1 - Failed to respond.  Section V.G.  VII.A.1 - Failed to respond.  Section VII – cancer alleged.  XI.A.1 - Failed to provide properly signed, undated, and completed authorization.  XI.A.4 - Failed to provide properly signed, undated, and completed authorization.  XI.A.5 - Failed to provide properly signed, undated, and completed authorization.  XII - Failed to provide signed and dated, declaration.	12/22/20

7.	Ragland, Arnold	10-cv- 04363	Watts Guerra, LLP	<p>I.E - Failed to respond.</p> <p>Section E – Representative information.</p> <p>II.C-K - Failed to respond.</p> <p>Sections II.C, D, G to J.</p> <p>III.F - Failed to respond.</p> <p>Section III.F</p> <p>IV.E - Failed to respond.</p> <p>- Witnesses</p> <p>XI.A.1, 6 - Failed to provide undated, completed and signed authorizations.</p> <p>XII - Failed attach completed, dated and signed declarations.</p>	7/6/20
8.	Wetzel, Winfield	2020- CV- 16130	Hollis Law Firm, P.A.	<p>III.A.1.b – Plaintiff still failed to provide how he has managed or treated his hypertension after discontinuing use of Valsartan products</p> <p>XI.B.2 – Plaintiff only produced eight (8) pages of medical records. Please produce Plaintiff’s complete medical records that are relevant to Plaintiff’s treatment for the alleged injury(ies) that he claims resulted from Valsartan usage. Also, no pharmacy records were produced for Giant Pharmacy. The produced pharmacy records that are titled as “Pharmacy Records – 2020.10.20 Giant_Food_PharmacyWetzel_Winfield” in Centrality are actually pharmacy records from Martin Pharmacy.</p>	2/10/21

9.	Futch, John	2020- CV- 16139	Hollis Law Firm, P.A.	III.A.1.b – Plaintiff states the he managed his hypertension with the use of Irebsartan and Losartan after discontinuing Valsartan products in the Amended PFS. However, the produced pharmacy records include usage of Irbesartan by the Plaintiff and do not include any usage of Losartan. Please clarify and supplement the response to this request.  XI.B.2 – No medical records were produced for the identified cancer date, being January 31, 2018. Also, no medical records were produced for the physician who prescribed Valsartan for the Plaintiff, being Gregory Glance, MD. No pharmacy records were produced for the following identified pharmacy: Moses Cone Hospital Pharmacy.	2/17/21
10.	Canfara, Michael- Est. of (Mashrique, P.)	2020- CV- 1834	Stark & Stark	No authorizations. PFS substantially incomplete.	02/09/2021

## **7. Joint Stipulation Regarding Dismissal of Torrent Private Ltd.**

On November 13, 2020, Torrent filed a joint stipulation with Plaintiffs regarding the dismissal of Torrent Private Limited (ECF 630). Torrent respectfully requests that the Court enter this joint stipulation.

## **8. Protocol for Dismissal of Certain Defendants Without Prejudice**

On March 4, 2021, an agreed upon Protocol for Dismissal of Certain Defendants Without Prejudice and Amended Stipulated Order regarding Dismissal of Peripheral Defendants to Include Losartan and Irbesartan was sent to the Court for entry. To date, the Orders have not been entered

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Special Master the Honorable Thomas Vanaskie  
The Honorable Karen Williams  
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therefore Defendants request that entry occurs or if the Court has questions, Defendants will be prepared to discuss.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Clem C. Trischler". The signature is fluid and cursive, with the first name "Clem" and last name "Trischler" clearly distinguishable.

Clem C. Trischler

c: All counsel of record (via ECF)